RESPONSE

The Examiner has raised a variety of rejections based on § 112, and rejections under § 102 based on the asserted content of various prior art references. Each such rejection is addressed in turn.

The recitation of the terms "conversion" and "pseudo" are removed for clarity.

With respect to the cited prior art references, none of these disclose the invention as claimed.

1. Section 102—Rapp et al.

The Rapp U.S. Patent Publication No. 2002/0108132-A12002 reference does not anticipate the pending claims. As previously noted, the present claims require rearrangement and expression. Rapp expresses a monoclonal antibody and functional rearrangement would be contrary to Rapp's stated purpose of expressing the monoclonal.

Rapp also does not enable a functional disruption of endogenous genes. The present rejection also appears to be based on principles inherency. The law of inherent anticipation under § 102 may only be applied when a prior art reference discloses a process that inevitably generates a later-claimed product. *See, e.g., Mehl/Biophile International Corp. v. Miligraum*, 192 F.3d 1362; 52 USPQ2d 1303 (Fed. Cir. 1999); *Glaxo v. Novepharm Ltd.*, 52 F.3d 1043, 1047; 34 USPQ2d 1565, 1567 (Fed. Cir. 1995). To establish that type of inherent anticipation, practice of the

prior art reference must produce the exact composition recited in the claims *each and every* time it is performed – it is *not* sufficient that there is a mere probability or possibility that the patented result will occur. *Id.* ("Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient"). To inherently anticipate, the patented compound must be "necessarily present" in the reference. *See Glaxo Group Ltd. v. Apotex, Inc.*, No. 03-1575, 2004 U.S. App. LEXIS 15489, at *22 (Fed. Cir. July 27, 2004) (*citing Schering Corp. v. Geneva Pharms, Inc.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003)).

The specific requirement of the inherent anticipation doctrine that the prior art produce the claimed invention each and every time it is practiced is particularly important in this case. The law is clear that evidence that the prior art process does not produce the patented compound every time it is performed, precludes inherent anticipation. *See Glaxo Inc. v. Novopharm Ltd.*, 52 F.3d 1043, 1047 (Fed. Cir. 1995), *see also 3M Unitek Corp. v. Ormco Co.*, 1042, 1048 (C.D. Cal. 2000).

When the prior art only facilitates the production of the claimed subject matter in amounts that are not "readily detectable," then inherent anticipation is lacking. This is underscored in *Schering Corp.*, 339 F.3d at 1379, which left undisturbed the holding in *In re Seaborg*, 328 F.2d 996 (C.C.P.A. 1964). In *Seaborg*, the Federal Circuit's predecessor court refused to find a prior art patent's process for manufacturing radioactive uranium to inherently disclose the co-production of

the claimed americium isotope. To the extent the latter would be present, it would be in a trivial amount. *See Seaborg*, 328 F.2d at 999; *Schering*, 339 F.3d at 1379.

Implicitly, the logic underlying *Seaborg* is that the production of trivial amounts of a claimed composition by a prior art process is "without profit to the art and without value as anticipation." *Pfizer, Inc. v. International Rectifier Corp.*, 545 F. Supp. 486, 509 (C.D. Cal. 1980); s*ee also Fromson v. Advance Offset Plate, Inc.*, 755 F.2d 1549, 1558 (Fed. Cir. 1985) (noting that an anticipation must enrich the prior art).

Nothing in the present record suggests that Rapp et al. could inevitably produce immunoglobulin molecules from a rearranged locus or produce detectable amounts to establish anticipation under § 102.

2. Buelow U.S.P. 7,129,084.

Buelow discloses only retroviral transfection that is clearly incapable of transferring an assembly of immunoglobulin genes capable of rearrangement into a recipient embryo. The retroviral transfection methodology is known to be size limited (usually less than 10-15kb)). No retroviral technology at the time of filing of the Buelow reference (or the present application) could carry the combination of human immunoglobulin genes so as to constitute an operative reference under 35 U.S.C. § 102 or § 103, which requires that the reference meet the threshold of enablement under §112. In 2008, the Federal Circuit in the Impax litigation ruled

that a prior art reference that acts as a § 102 reference must be enabling of the subject matter of the claim in question. The legal requirement for such a reference is as follows:

> In order to anticipate a claimed invention, a prior art reference must enable one of ordinary skill in the art to make the invention without undue experimentation.
> *Finisar Corp. v. DirecTV Group, Inc.*, 523 F.3d 1323, 1336 (Fed. Cir. 2008) (citing *In re Omeprazole Patent Litig.*, 483 F.3d 1364, 1379 (Fed. Cir. 2007)). In other words, the prior art must enable the claimed invention. *Minn. Mining & Mfg. Co. v. Chemque, Inc. (3M)*, 303 F.3d 1294, 1301 (Fed. Cir. 2002). The "undue experimentation" component of that equation examines (1) the quantity of experimentation; (2) the amount of direction or guidance present; (3) the presence or absence of working examples; (4) the nature of the invention; (5) the state of the prior art; (6) the relative skill of those in the art; (7) the predictability or unpredictability of the art; and (8) the breadth of the claims. *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). (emphasis added)
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> Whether a prior art reference is enabling presents a question of law based upon underlying factual findings. *3M*, 303 F.3d at 1301.

545 F.3d 1312 at 1314-15.

The Buelow reference fails this standard. Specifically, the Buelow reference does not disclose actual transgenesis by any technique other than a retroviral vector and such vectors are incapable of harboring a large enough assembly of immunoglobulin genes to undergo rearrangement.

In the absence of an enabling disclosure of the subject matter of the pending claims, the Buelow reference is not prior art to the present claims and should not be part of a § 102 rejection.

3. Singh et al.

With respect to the rejection over Singh, U.S. Patent Publication No. 2002/0028488, as noted previously, the Singh publication is a farce. Singh et al. merely copied the United States patent of Kucherlapati et al. (cited in the earlier action) that relates only to expression of human immunoglobulins in transgenic mice. At the very least, Singh et al. is conspicuously non-enabling for the subject matter of the present claims because the specific gene modifications and restriction sites, etc., and essentially all functional portions of the Singh et al. publication, are directed to the mouse genome, not the chicken genome. Therefore, the teachings of Singh et al. obviously fail the requirement of the Impax case requiring enablement of the claimed subject matter of a reference used to anticipate under § 102.

The Commissioner is also authorized to charge $820.00 for the four month extension fee to Orrick Herrington & Sutcliffe's Deposit Account No. 150665 and charge any fees required by the filing of this papers, and to credit any overpayment to Orrick Herrington & Sutcliffe's Deposit Account No. 150665.

Respectfully submitted,

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